



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military

Combat; Correction

AGENCY: Department of Health and Human Services, Office of the Secretary

ACTION: Notice, Correction.

SUMMARY: The Department of Health and Human Services is correcting a notice that appeared in the Federal Register on July 16, 2018. The notice announced the Secretary's Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage During an Emergency Involving Agents of Military Combat pursuant to section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act. On July 9, 2018, the Secretary declared that circumstances exist justifying the authorization of emergency use of freeze dried plasma (FDP) for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. This notice is correcting the July 16, 2018 notice to correctly state the Secretary's declaration.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

In the Federal Register of July 16, 2018 (83 FR 32884) appearing on page 32884 in FR Doc. 2018- 15152 the following corrections are made:

1. Title, change the title of the notice to “Declaration Regarding Emergency Use of Treatment for Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat.”
2. Summary section, change the second paragraph to: “ On the basis of this determination, on July 9, 2018, the Secretary declared that circumstances exist justifying the authorization of emergency use of freeze dried plasma (FDP) for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.”
3. Supplementary Information section, subpart I, Background, second paragraph second sentence, delete “French” before “FDP.”
4. Supplementary Information section, subpart III, Determination of the Secretary of Health and Human Services, change paragraph 1 to: “On July 9, 2018, on the basis of the Deputy Secretary of Defense’s determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of FDP for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not

available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.”

Dated: July 25, 2018.

Ann Agnew,
Executive Secretary to the Department,
U.S. Department of Health and Human Services.

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